

Louisiana Medicaid Preferred Drug List Program Overview and Results

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Prepared By:

Provider Synergies, L.L.C Magellan Medicaid Administration, Inc.

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OVERVIEW

The Louisiana Department of Health and Hospitals (DHH) preferred drug list (PDL) program has been in operation since 2002 by Provider Synergies, L.L.C. Provider Synergies is an affiliate of Magellan Medicaid Administration, Inc.

Louisiana is entering the ninth year as one of eight states participating in the multi-state purchasing program, The Optimal PDL Solution (TOP\$). Louisiana was one of three states that initially participated in the multi-state purchasing pool, TOP\$, in 2005. The eight states now participating in TOP\$ are Louisiana, Maryland, Delaware, Idaho, Pennsylvania, Wisconsin, Nebraska, and Connecticut.

This review summarizes the results of the PDL program for fiscal year 2012-2013 (FY2013) and the first two quarters of fiscal year 2013-2014 (FY2014).

I. MAJOR DEVELOPMENTS IN FY2013

In March 2010, President Obama signed the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, together known as the Affordable Care Act (ACA), into law. The ACA included stipulations that had a significant impact on both federal and supplemental Medicaid drug rebates. These regulations went into effect 01 OCT 2013.

In 2012, ACA impact for Louisiana was seen in the partial movement of coverage for Medicaid pharmacy services from a fee-for-service (FFS) model to managed care organizations (MCOs). With MCO utilization eligible for the collection of federal rebates, several states have elected to employ MCOs for coordination of benefits and continue to collect federal rebates for this utilization. Utilization is not eligible for supplemental rebates, however, if the MCOs are permitted to use their own formularies. Louisiana elected for this option for a portion of Medicaid lives, decreasing the number of FFS lives to about 630,000.

For FY2013, the state altered their reimbursement methodology, which created a more aggressive pricing model for payments to pharmacies. This new formula for generic reimbursement is actual acquisition cost (AAC) + 10%; for brands, the formula is AAC + 1%. The dispensing fee has been increased to \$10.51. This enabled the state to take advantage of inexpensive generics and create the opportunity for significant switch savings. This is the savings associated with moving pharmacy utilization from more expensive products to less expensive products, provided that clinical effectiveness is similar. With this methodology in place, all PDL classes were re-evaluated for appropriate preferred products and the November TOP\$ review incorporated the new methodology in order to make projections under the new reimbursement model.

Analysis

The ACA initially had a significant and immediate impact on states' shares of rebates. Magellan Medicaid Administration and Provider Synergies have observed that the negative impact on supplemental rebates has been somewhat negated by competition in the pharmaceutical marketplace. Also, expanded Medicaid enrollment across participating states encourages manufacturers to offer supplemental rebates to ensure the positioning of their drug products on Medicaid PDLs.

With the removal of nearly half of the Medicaid lives from the FFS group, overall spend will decline for the remaining lives, but federal and supplemental rebate collections by the state will also be reduced. .

II. SAVINGS METHODOLOGY

There are two ways that Louisiana derives savings from the PDL: (1) supplemental rebates and (2) market shift savings. Both types of savings are listed in the PDL Supplemental Rebate & Market Shift Report that is sent quarterly to DHH.

a. Supplemental Rebates = (Supplemental Rebate Per Unit x Number of Units Dispensed)

Supplemental rebate per unit is calculated in accordance with the supplemental rebates offered for products (identified by 11-digit NDC) that are included on the PDL.

The predominant calculation type that manufacturers may use is called a "guaranteed net unit price" (GNUP). GNUP calculations are different from total percent offers because they protect the state from price increases through manufacturer price guarantees. If the manufacturer increases its price, it makes up the price increase penny for penny in additional rebates. For example, if the manufacturer offered a GNUP of \$0.60 per unit, its federal rebate was \$0.25 and the AWP of the product was \$1.00, the manufacturer would pay a \$0.15 supplemental rebate. Should the manufacturer then increase its price to \$1.10, the rebate liability would also increase, from \$0.40 to \$0.50 (i.e. \$1.10 - \$0.60). The supplemental rebate would increase from \$0.15 to \$0.25.

b. Market Shift Savings = Total Savings - Supplemental Rebates

Market shift savings occur when a patient on a product not included on the PDL changes therapy to a preferred medication that is less expensive. Essentially, this is a measure of cost avoidance for the Medicaid program.

For example, suppose that a non-preferred medication costs the Louisiana Medicaid program \$40 per prescription (after all rebates are applied), and the physician changes a recipient's drug regimen to replace that medication with one on the PDL that costs \$30 per prescription (again, after application of all rebates). As a result of the change, the Medicaid program saves \$10 each

time the recipient receives the new prescription versus incurring the additional cost had the patient not changed drugs.

In some cases, products are placed on the PDL and generate savings even without offering a supplemental rebate. This situation occurs either because the product is less expensive or because it has a large federal rebate that renders the net price paid by DHH lower than the cost of competing therapies.

Market shift savings for each class are calculated for each drug name in the class, and then summed for the class total. Total savings is the sum of market shift savings and supplemental rebate savings.

III. REVIEW OF MAJOR THERAPEUTIC CLASSES

The continuous cycle of patent expirations with the development of new PDL classes such as Hypoglycemics, SGLT2, leaned more heavily on the patent expiration side for FY2013 in terms of determining the source of impact on the savings from the PDL program. Classes that historically have resulted in large savings for the state have seen generics cause them to move from supplemental rebate-driven savings to market shift savings. Examples include Antipsychotics and Neuropathic pain. The following is a summary of the major therapeutic classes that generate a significant amount of savings for the PDL program.

Stimulants and Related Agents

Stimulants and Related Agents are used for the treatment of Attention Deficit/Hyperactivity Disorders and Narcolepsy. High amounts of supplemental rebates drive the significant savings in this class. Despite several products becoming available as generics in recent years, those generic costs remain high relative to the price of the brands, net of all rebates. Examples include Adderall XR and Concerta, two major brands that command high market shares. For 2013 the majority of supplemental savings comes from Adderall XR, Vyvanse, Focalin XR, and Intuniv. The postitive market share savings comes from the continued shift from higher cost Concerta to its generic.

SAVINGS: Total supplementals and market shift savings for the Stimulants and Related Agents for FY2013 was over \$11 million. The first two quarters of FY2014 have estimated savings for the Stimulants and Related Agents class of about \$5.5 million.

Glucocorticoids, Inhaled

Glucocorticoids, Inhaled, also called Inhaled Corticosteroids, are generally used in the management of asthma and chronic obstructive pulmonary disease (COPD). Over the last two years, Pulmicort Respules has had a generic product available. The shifting of market share from brand to generic resulted in increased costs due to the high cost of the generic. Other changes in 2013 include the addition of high cost brands into the class such as Breo-Ellipta.

SAVINGS: In FY2013, the supplemental plus market shift savings total for the Glucocorticoids, Inhaled was \$1.75 million. The first two quarters of FY2014 have estimated savings for the Glucocorticoids, Inhaled class of about \$765,000.

Cephalosporins and Related Agents

The Cephalosporins and Related Agents treat a number of common infections, and selection of a particular agent to treat a specific infection is often empirical and without the availability of microbiology culture and sensitivity data of the pathogen. The cephalosporins class consists of mostly generic products with a few branded exceptions including Suprax and and Cedax. Utilization of these brands resulted in significant accumulation of supplemental rebates. The bulk of the supplemental savings comes from the higher cost Suprax suspension shifting to the lower cost generics in the class.

SAVINGS: The supplemental plus market shift savings total for the Cephalosporins and Related Agents class consist of both market share movement to lower cost generic preferred agents and from the accrual of supplemental rebates. For FY2013, cost avoidance due to market shift savings and supplemental rebates totaled approximately \$6 million for the Cephalosporins and Related Agents. The first two quarters of FY2014 have estimated savings for the Cephalosporins and Related Agents class of \$2.6 million.

Platelet Aggregation Inhibitors

The platelet aggregation inhibitors class has generated savings in that the class is fairly unchanged and litigation held up generics entering the class, however the class is no market share driven in that lower cost generics generate significant savings over the non-preferred brand agents.

SAVINGS: For FY13, the savings for the category were about \$850,000. The first two quarters of FY2014 have estimated savings for the Platelet Aggregation Inhibitors class of \$200,000 as utilization in this class becomes further driven by inexpensive generics.

Antipsychotics

The Antipsychotics are important in the management of symptoms of bipoloar mania and schizophrenia. Supplemental rebate savings continue to be high based on the volume of utilization of these agents. Latuda, Fanapt, and Seroquel XR are generating the supplemental savings. The market share shift savings is coming from Geodon, Seroquel, Invega Sustenna, and Abilify shifting to less costly products in the class.

SAVINGS: For FY2013, the supplemental plus market shift savings totaled \$4 million due to an optimized PDL selection of preferred agents. The first two quarters of FY2014 have estimated savings for the Antipsychotics class of nearly \$1.6 million.

Leukotriene Modifiers

Leukotriene modifiers continue to be a class with large savings dollars even though there haven't been any new entrants into the class.

SAVINGS: The supplemental plus market shift savings savings for FY2013 was \$4 million for this class. The first two quarters of FY2014 have estimated savings for this class of \$1.7 million.

Growth Hormone

Savings projections are consistently met for this class due to constant utilization and a relatively static list of preferred agents. For several years, this class has been set at three preferred options and market shares tend to fall in line accordingly, as providers are pleased with the selections made by the P&T Committee and the state. The positive savings comes mostly from large supplemental rebates from Norditropin and Norditropin AQ. The negative savings is a result of lower cost Saizen shifting to Norditropin.

SAVINGS: For FY2013, the supplemental plus market shift savings totaled \$1.2 million in this class. Savings for the first two quarters of FY2014 are projected to be \$930,000.

Number of Therapeutic Classes Reviewed

The number of PDL classes reviewed has nearly doubled since the inception of the TOP\$ program, culminating with the review of 83 classes during the FY2013 P&T meetings.

PDL Compliance

PDL Compliance is the percentage of the number of dispensed prescriptions that are preferred divided by the total number of dispensed prescriptions that are subject to the PDL. In FY2013, the PDL Compliance average rate was 91.2 percent. FY2014's rate was the same through the first two quarters.

IV. REPORTED SAVINGS FY2012 THROUGH FY2013

Factors affecting the PDL program: United States Health Care Reform

As referred to in Section I (Major Developments in FY2011-2012), the ACA results in an 8% increase in the federal rebate on the majority of single source brand (SSB) drugs and 2% on generics, an increase that is exempted from State FMAP (Federal Medical Assistance Percentage) regulations. This act reduced State Medicaid supplemental rebate dollars initially for those drugs under contract starting in January 1, 2010.

b. Savings Results

In FY2012/13 the cost avoidance savings with the PDL program totaled \$40.5 million. This number was \$38.2 million in FY2013.

The ACA changes to the Federal Rebate program have negatively affected the accrual of supplemental rebates since its effective date in FY2010.

Table 1: Reported Savings by Quarter FY2012, FY2013

Savings Results FY 2012
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Calendar Qtr	LA Fiscal Qtr	Quarterly Reported Savings	Comment
1Q12	Q312	\$ 10,251,080	Actual 1Q2012 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
2Q12	Q412	\$ 10,564,139	Actual 2Q2012 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
3Q12	Q113	\$ 11,748,842	Actual 3Q2012 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
4Q12	Q213	\$ 9,680,080	Actual 4Q2012 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)
Totals		\$ 42,244,140	

Savings Results FY 2013						
Calendar Qtr	LA Fiscal Qtr	Quarterly Reported Savings	Comment			
1Q13	Q313	\$ 9,820,689	Actual 1Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)			
2Q13	Q413	\$ 9,159,758	Actual 2Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)			
3Q13	Q114	\$ 9,701,738	Actual 3Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)			
4Q13	Q214	\$ 9,500,000	Actual 4Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)			
Total		\$ 38,182,185				

V. ESTIMATED SAVINGS FOR FY2014

a. Factors affecting the PDL program in FY2013

i. New generic medications

The pharmaceutical market is entering a period of high occurrences of patent expirations of blockbuster drugs. Examples of this impact on the PDL program could be seen in the past year with Cymbalta, Lidoderm, and Concerta. Typically, generics are thought to be lower cost than branded medications. More often, the newly released generics are priced at a premium to the net-net cost of the branded medications in Medicaid. The new higher cost generics will likely negatively impact the savings of the PDL program in the short term (usually about six months). Price erosion typically occurs over one year. The coming year will not see the same large number of blockbuster patent expirations, but some will continue to occur.

Savings estimates for FY2014 are a total of \$38 million.

Actual savings may be different from projections due to some or all of these possibilities. Large population changes as a result of economy, hurricanes or other disasters would have a

potentially large effect on the population. If Pharmacy benefits program is placed into CCN programs, the smaller population in FFS would accrue less supplemental rebates. New drugs will enter the market – unforeseen impact on drug utilization and unknown participation in supplemental rebate program. Drugs may enter the market for diseases that are currently not treated. Recalculation of AMP and the changes in FUL calculation may have significant impact on pricing of drugs. The level of aggressiveness of a state MAC list can impact the number of branded drugs listed on the PDL. Fewer branded drugs or lower utilization of branded products will result in lower supplemental rebates. Limiting the number of branded products in a class would likely lower supplemental rebates for some drug classes or potentially for the whole PDL program. Change in savings reporting methodology. FMAP changes will impact the state's share of all rebates. New changes in Federal Medicaid rules and regulations regarding drug coverage, drug pricing or rebate programs may impact the savings estimates.

Table 2: Estimated Savings by Quarter FY2014

Savings Projections FY 2014						
Calendar Qtr	LA Fiscal Qtr	Estimated Supplemental		Estimated Switch	Comment	
3Q13	Q1 14	\$ 9,701,738	\$	(2,676,841)	Actual 3Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)	
4Q13	Q2 14	\$ 9,500,000	\$	(2,805,966)	Actual 4Q2013 (reflecting CMS federal rebates amounts under rebate rules established by ACA.)	
1Q14	Q3 14	\$ 8,991,137	\$	(2,100,000)	Estimated 1Q2014. Projections may be impacted by list of factors below.	
2Q14	Q4 14	\$ 8,687,125	\$	(2,211,000)	Estimated 2Q2014. Projections may be impacted by list of factors below.	
Totals		\$ 36,880,000	\$	(9,793,807)		

Actual savings may be different from projections due to following various factors: Medicaid expansion with eligibility. The percent of Federal share of the newly eligible population changes over several years. Drug utilization may change depending on the health of the newly eligible population. Large population changes as a result of economy, hurricanes or other disasters would have a potentially large effect on the population. If Pharmacy benefits program is placed into CCN programs, the smaller population in FFS would accrue less supplemental rebates. New drugs will enter the market – unforeseen impact on drug utilization and unknown participation in supplemental rebate program. Drugs may enter the market for diseases that are currently not treated. Recalculation of AMP and the changes in FUL calculation may have significant impact on pricing of drugs. The level of aggressiveness of a state MAC list can impact the number of branded drugs listed on the PDL. Fewer branded drugs or lower utilization of branded products will result in lower supplemental rebates. Limiting the number of branded products in a class would likely lower supplemental rebates for some drug classes or potentially for the whole PDL program. Change in savings reporting methodology. FMAP changes will impact the state's share of all rebates. New changes in Federal Medicaid rules and regulations regarding drug coverage, drug pricing or rebate programs may impact the savings estimates.

VI. FEATURES OF THE LOUISIANA MEDICAID PDL THAT IMPACT SAVINGS

Strengths: Louisiana participates in the multi-state purchasing pool and benefits from volume purchasing but maintains autonomy in PDL decisions. States receive, in some cases, better offers for supplemental rebates as a part of the TOP\$ program compared to other single states soliciting for supplemental rebates.

The change to the reimbursement formula in 2012 will allow Louisiana to better take advantage of low prices on generics and not rely so heavily on supplemental rebates for program savings.

Weakness: The feature of Louisiana's program that possibly affects savings to the greatest extent is the statutorily mandated continuity of care process. Under the continuity of care program, a patient whose prescription medication is non-preferred may continue to take the non-preferred medication for up to six months or five refills. While this approach has minimized the initial impact of the PDL on patients, usage has not shifted as quickly to preferred medications, and savings have not been realized as quickly as would otherwise have been possible.

The current PDL program allows new drugs to process without prior authorization until reviewed by the Pharmaceutical and Therapeutics Committee. New drugs gain market share quickly before the P&T Committee has an opportunity to review the data on the new drug. An evaluation of this process should be considered to determine if new drugs should require prior authorization prior to the P&T Committee's review of the safety and efficacy data.

VII. SUMMARY

The Preferred Drug List generates cost savings in two ways. First, supplemental rebates are collected from pharmaceutical manufacturers for their inclusion as a preferred product. Secondly, by requiring a prior authorization (PA) on non-preferred products, claims are shifted from more expensive medications to less costly alternatives.

One thing to note for 2013 was the cancelation of the spring P&T meeting which caused the savings to not be fully maximized as no recommended changes were implemented.

The LDHH PDL program continues to be extremely successful. Savings for FY2013 were \$38.2 million. For the first two quarters of FY2014, the savings are \$19.2 million with the estimated year-end savings of \$38.4 million.

Similar to other states with competitive selection based PDL models, prices have continued to drop or at worst stabilize in each subsequent review of each class. Louisiana's leadership in establishing the TOP\$ multi-state program accelerated this trend.